

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1, 3, 4, and 12-41 are pending and directed to an isolated antigen (claims 1, 3, 4, and 36-41), a ligand that recognizes the antigen (claims 12-19 and 33-35), a composition comprising the ligand (claims 20-30), and a method for treating a cancer disease (claims 31 and 32). Claims 12-35 are labeled as withdrawn in response to the earlier restriction requirement. Applicants request the rejoinder and examination of claims 12-35 at such time as a pending claim is indicated allowable inasmuch as claims 12-35 depend from elected claim 1 and contain similar limitations to those recited in the other pending claims under examination.

*Amendments to the Specification*

The specification has been amended to capitalize the trademarked term VECTASTAIN<sup>TM</sup> and to add a generic noun thereafter.

No new matter has been added by way of these amendments to the specification.

*Amendments to the Claims*

The claims have been amended to point out more particularly and claim more distinctly the invention. In particular, claim 1 has been amended to recite the features of claims 2 and 10 (now canceled). Claims 3 and 4 have been amended to no longer recite the term “existing” and to clarify the claim language as supported by the specification at, for example, page 7, lines 6-17. Claims 2 and 5-11 have been canceled. Claims 36-41 are new and are supported by the specification at, for example, page 7, lines 6-20.

Withdrawn claims 18 and 19 have been amended to clarify the claim language. Additionally, withdrawn claims 31-33 have been amended to recite the features of newly amended claim 1.

No new matter has been added by way of these amendments to the claims.

*Summary of the Office Action*

The Office Action contains the following objections and rejections:

- (1) The Office objects to the specification for not capitalizing trademarks.
- (2) The Office objects to claim 10 for reciting “in the Sequence Listing.”
- (3) The Office rejects claims 1-9 under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter.
- (4) The Office rejects claims 1-11 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.
- (5) The Office rejects claims 5-9 under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement and written description.
- (6) The Office rejects claims 1 and 5-11 under 35 U.S.C. § 102(b) as allegedly anticipated by Chiavegato et al. (*Virchows Archiv.*, 426: 77-86 (1995)).
- (7) The Office rejects claims 1-4 under 35 U.S.C. § 102(b) as allegedly anticipated by EP 0 399 257 (“the ‘257 publication”).
- (8) The Office rejects claims 1 and 5-11 under 35 U.S.C. § 102(b) as allegedly anticipated by WO 01/75067 (“the ‘067 publication”) as evidenced by Saez et al. (*PNAS*, 97: 1164-1168 (1990)).

Reconsideration of these rejections is hereby requested.

*Discussion of the Specification Objection*

As requested by the Office, the specification has been amended to capitalize the trademarked term VECTASTAIN<sup>TM</sup>. Applicants also have added a generic noun after the trademark. Accordingly, Applicants request the withdrawal of the objection to the specification.

*Discussion of the Claim Objection*

The Office objects to claim 10 for reciting “in the Sequence Listing.” Claim 10 has been canceled. Therefore, the objection to claim 10 is moot and should be withdrawn.

*Discussion of the Utility Rejection*

The Office contends that claims 1-9 are directed to non-statutory subject matter. Claim 1 (and, thus, the claims dependent thereon) has been amended to recite an “isolated antigen.” Accordingly, Applicants request the withdrawal of the utility rejection.

*Discussion of the Indefiniteness Rejections*

The Office contends that it is unclear in claim 1 what is positioned at the formation of the tumor mass. Claim 1, as amended, recites that the antigen has a part which is exposed on the surface of a cell positioned at the formation of a solid tumor. Accordingly, one of ordinary skill in the art would understand that the cell is positioned at the formation of the tumor.

The Office contends that “the solid tumor” in claims 3 and 4 lacks antecedent basis. Claim 1, as amended, recites that the tumor is a solid tumor, thus providing proper antecedent basis for “the solid tumor” in claims 3 and 4.

The Office contends that claims 3 and 4 are indefinite because the relationship between the amount of antigen being measured on the solid tumor and the amount of antigen of the cultured cell of the solid tumor is unclear. Claims 3 and 4 have been amended to clarify the claim language. Claim 3, as amended, recites that the antigen is produced in a greater amount by the cells of the solid tumor formed by subcutaneous transplantation of a cultured cancer cell than by the cultured cancer cell. Claim 4, as amended, recites that the amount of the antigen on the surface of the cells of the solid tumor formed by subcutaneous transplantation of a cultured cancer cell is greater than the amount of antigen on the surface of the cultured cancer cell. The specification describes antigen comparison methods at, for example page 7, lines 6-20; and page 14, line 11, through page 15, line 2. Accordingly, one of ordinary skill in the art would understand the meaning of claims 3 and 4.

The Office contends that claims 3 and 4 are indefinite because the phrase “the existing amount” is unclear. Claims 3 and 4, as amended, no longer recite “existing.”

The Office contends that “the cell surface” in claim 4 lacks antecedent basis. Claim 4, as amended, recites “a surface of the cell.”

The Office contends that claim 10 is unclear. Claim 10 has been canceled.

For the above-described reasons, the pending claims are sufficiently clear, and the indefiniteness rejections should be withdrawn.

*Discussion of the Written Description and Enablement Rejections*

The Office contends that the specification does not adequately describe or enable the entire scope of claims 5-9. These claims have been canceled. Accordingly, the Section 112, first paragraph, rejections are moot and should be withdrawn.

*Discussion of the Anticipation Rejections*

The pending claims, as amended, are directed to an isolated antigen having a part which is exposed on the surface of a cell positioned at the formation of a solid tumor formed by subcutaneous transplantation of a cultured cancer cell, wherein the antigen comprises residues 600-1,960 of SEQ ID NO: 17.

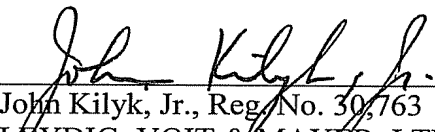
Chiavegato et al., the ‘257 publication, and the ‘067 publication do not teach or suggest all of the elements of the pending claims. For example, Chiavegato et al. and the ‘067 publication do not disclose that the cell is positioned at the formation of a solid tumor formed by subcutaneous transplantation of a cultured cancer cell, as required by the pending claims. The ‘257 publication does not teach or suggest that the antigen comprises residues 600-1,960 of SEQ ID NO: 17, as required by the pending claims.

For these reasons, the subject matter of the pending claims, as amended, is not anticipated by the cited references. Accordingly, Applicants request the withdrawal of the anticipation rejections.

*Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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